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REMARKS/ARGUMENTS

Summary of Amendments, status of claims

Claim 18 is canceled.

Claim 24 is amended so that antecedent basis is found in claim 20, from which it depends. The amendment is made at this time, rather than earlier, since this is the first opportunity for applicant to respond to a rejection of claim 24, and/or, alternatively, to place the application in better condition for consideration on appeal. Entry is solicited.

Claims 1-3, 8-12, 16-17, 20 and 24 are pending.

Rejections under 35 USC 112, second paragraph

Claims 18 and 24 stand rejected under 35 USC 112, second paragraph.

Claim 18 recites the limitation "the plurality of proteonic cancer markers from different types of cancer cells". There is said to be insufficient antecedent basis for this recital in parent claim 20.

Claim 24 recites the limitation "the plurality of proteonic cancer markers from different types of cancer cells." There is said to be insufficient antecedent basis for this recital in parent claim 20.

Claim 18 is canceled.

Claim 24 is amended by deleting the language forming the basis of the rejection and replacing it with "the single type of cancer cells" which is supported verbatim in claim 20.

Reconsideration and withdrawal of this rejection is therefore requested.

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Rejections under 35 USC 112, first paragraph

Office Action, Section 6

Claims 1-3, 8-12, 16-18, 20 and 24 stand rejected under 35 USC 112, first paragraph, for failure to comply with the enablement requirement. It is stated on page 5 of the office action, first full paragraph, that

"One cannot extrapolate the teaching of the specification to the enablement of the claims because the specification gives insufficient guidance and direction as to what predetermined value in the ELISA test is indicative of a positive screening test for cancer. . . .the only predetermined value taught in the specification a titer of 1:1000 is not predictably useful for indicating a positive test for cancer as the claimed method gives values above 1:1000 in individuals that are apparently normal and also produces values below 1:1000 in individuals who appear to have cancer . . . " This rejection is traversed.

MPEP 2164 discusses the enablement requirement. The factors to be considered are (A) The breadth of the claims (B) The nature of the invention © The state of the prior art (D) The level of one of ordinary skill (E) The level of predictability in the art (F) The amount of direction provided by the inventor (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Each of the claims is directed toward "A non-invasive cancer screening method". The difference between a screening method and a diagnostic method is that a screening method assigns nonsymptomatic patients to a risk category, whereas a diagnostic method determines whether or not a patient has a disease. The arguments set forth in section 6 relate largely to diagnostic methods, which is not the nature of the invention. When the claimed screening method is carried out, a patient that has a test result over a predetermined value (for example, 1000) is at higher risk for cancer than a patient that has a test result of less than a predetermined value (for example, less than 1000). As is well known to those skilled in the art, (persons possessing doctorate degrees and several years of experience) the predetermined value can be moved higher to reduce the

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number of false positive test results, or lower to reduce the number of false negative test results. There is no magic number, and the failure of the specification to provide one does not establish a meritorious case of nonenablement. Based on the description and examples, and the skill level of the art, a suitable predetermined value for the screening test cutoff can be determined without unreasonable experimentation.

The examples in the specification show the recovery of proteonic cancer markers used in the making of antibodies from in vitro sources. The claims would include proteonic cancer markers from in vivo sources. Proteonic cancer markers from in vivo sources would be expected to produce more efficacious antibodies for carrying out the invention than those from in vitro sources, since "real life" antigens would produce antibodies which effective against them. The situation is non-analogous to (non-antibody-based) cancer drug efficacy, where in vitro efficacy is not a good predictor of in vivo efficacy. Additionally, the invention has been demonstrated in a living system, and this is shown in the examples. Because the specification shows antibody operability from PCMs derived from in vitro sources, antibody operability for PCMs derived from in vivo sources is fairly established.

In view of the forgoing remarks, reconsideration and withdrawal of the nonenablement rejection is requested.

Rejections under 35 USC 112, first paragraph

Office Action, Section 7

Claims 1-3, 8-12, 16-18, 20 and 24 stand rejected for failure to comply with the written description requirement. On page 11 of the office action, it is stated "Because the genus of a mixture from different types of cancer cells containing proteonic cancer markers identified and markers not yet identified is not adequately described, the method claims relaying on said genus are also not adequately described." On page 12 of the office action, it is stated "the genus is only described as a definition by function (i.e. the ability to form polyclonal antibodies), and beyond that example of a mixture of markers from the HT-29/breast cancer, Diji/colon cancer, CCL-

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13/liver, and Sk-ov-3/ovarian cancer cells, one of skill in the art cannot readily visualize or recognize the identity of members of the genus." It is stated on page 11 of the office action that "One of skill in the art can reasonably conclude that applicant was not in possession of a genus of "a mixture from different types of cancer cells containing proteonic cancer markers identified and markers not yet identified" at the time the invention was filed."

The recitation of the "genus" in the claims must be evaluated in view of the prior art and the level of skill in the art in order to determine whether it is adequately disclosed. Claim 1 recites: "providing a mixture of proteonic cancer markers from different types of cancer cells, said mixture containing proteonic cancer markers identified and markers not yet identified". Different types of cancer cells were known to the art. It was known that the cells produced proteonic cancer markers, some of which were known and others not. What was not known was putting these proteonic cancer markers in a mixture. The level of skill in the art is mostly likely a doctorate degree and several years of research experience. Making a mixture of known materials is well within the level of skill. Furthermore, the specification provides a description of 4 "species" within the "genus" and demonstrates operability for them, and these are set forth in claim 16 as "a mixture of proteonic cancer markers obtained from breast, liver, colon, and ovarian cancers, said mixture containing proteonic cancer markers identified and markers not yet identified." The specification furthermore mentions at page 5, lines 9-14 that the "cell line can be selected from the group consisting of a breast cancer cell line, a lung cancer cell line, a stomach cancer cell line, a liver cancer cell line, a colon cancer cell line, an ovarian cancer cell line, a cervical cancer cell line, a mouth/pharynx cancer cell line, a skin cancer cell line, a pancreatic cancer cell line, a testes cancer cell line, a brain tumor cell line, and a prostate cancer cell line." Because of these factors, and because of the disclosure of representative species over the scope of the claims, it is submitted that all claims are in compliance with the written description requirement.

The Lilly case is not on point, as the unsupported (and un-described) "genus" there was a generically claimed, inadequately characterized, composition of matter which was asserted to be

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novel. The present claims are methods, and the materials employed are known and/or obtainable using the teaching of the specification and characterized functionally and by way of example.

Reconsideration and withdrawal of this written description rejection is therefore requested.

Rejections under 35 USC 112, first paragraph

Office Action, Section 8

Claims 1-3, 8-12, 16-18, 20 and 24 stand rejected under 35 USC 112, first paragraph, for failing to comply with the written description requirement. It is asserted that the claim (as previously amended) contains subject matter which was not described in the specification to demonstrate possession of the invention.

Claim 1 recites: "a) providing a mixture of proteonic cancer markers from different types of cancer cells, said mixture containing proteonic cancer markers identified and markers not yet identified;"

Claim 16 recites: " a) providing a mixture of proteonic cancer markers obtained from breast, liver, colon, and ovarian cancers, said mixture containing proteonic cancer markers identified and markers not yet identified;"

These recitations are said to have no clear support in the specification and claims as filed. The basis for the assertion is said to be that "there is nothing in the specification to suggest the broadly claimed mixture of proteonic markers from different types of cancer cells or breast, liver, colon, and ovarian cancers, which includes cells directly obtained from tumors in addition to markers from cancer cell lines." It is said that the subject matter set forth in claims broadens the scope of the invention as originally disclosed in the specification.

Dealing with this last point first (broadening amendment contention), claim 1 as originally filed

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read as follows:

1. A process comprising

a) bringing together a reagent containing antibodies made against a mixture of proteonic cancer markers with a human saliva sample to form an assay sample, and

b) determining whether an immunological reaction has occurred in the assay sample.

Current claim 1 reads as follows:

1. (Previously presented) A noninvasive cancer screening method comprising

a) providing a mixture of proteonic cancer markers from different types of cancer cells, said mixture containing proteonic cancer markers identified and markers not yet identified;

b) forming polyclonal antibodies against the mixture;

c) forming a reagent from said polyclonal antibodies;

d) obtaining a saliva sample from a human not diagnosed with cancer;

e) bringing said saliva sample together with the reagent to form an assay sample, and

f) assaying the assay sample by simple ELISA test to determine whether an immunological reaction has occurred in the assay sample,

wherein ELISA test results higher than a predetermined value are indicative of a positive screening test for cancer.

Current claim 1 is clearly much narrower than application claim 1.

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Step (a) of application claim 1: "a) bringing together a reagent containing antibodies made against a mixture of proteonic cancer markers with a human saliva sample to form an assay sample" is replaced by steps (a) through (e) of current claim 1 "a) providing a mixture of proteonic cancer markers from different types of cancer cells, said mixture containing proteonic cancer markers identified and markers not yet identified; b) forming polyclonal antibodies against the mixture; c) forming a reagent from said polyclonal antibodies; d) obtaining a saliva sample from a human not diagnosed with cancer; e) bringing said saliva sample together with the reagent to form an assay sample". Zeroing in on the reagent, application claim 1 recites "reagent containing antibodies made against a mixture of proteonic cancer markers". Current claim 1 further requires that the markers be from different types of cancer cells and contain cancer markers identified and not yet identified.

Clearly, the claim has not been broadened.

Regarding the second basis of the rejection, that "there is nothing in the specification to suggest the broadly claimed mixture of proteonic markers from different types of cancer cells or breast, liver, colon, and ovarian cancers, which includes cells directly obtained from tumors in addition to markers from cancer cell lines" it is noted that the line of argument would have applied to application to claim 1 as originally filed, see above, i.e., the rejection is belated as well as inappropriate. It is not, in any event, justified by applicant's amendments. For reasons pointed out in response to the section 7 rejection, possession of the claimed invention at the time the application was filed has been adequately demonstrated.

Reconsideration and withdrawal of this rejection is therefore requested.

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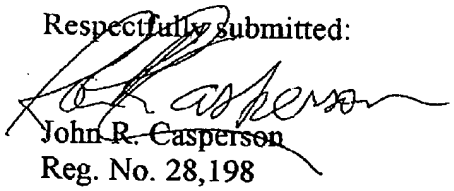
Conclusion

In view of the foregoing, reconsideration and withdrawal of all grounds of rejection and early notice of allowance is respectfully solicited.

Respectfully submitted:



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